**Textile Products Division** 

CIBA-GEIGY Corporation P.O. Box 18300 Greensboro, North Carolina 27419-8300 Telephone 919 632 6000

Contains NO CBI

8EHQ-92-12301

88920010511

October 9, 1992



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CIBA-G

Document Processing Center (TS-790) Office of Toxic Substances Environmental Protection Agency 401 M. Street, SW Washington, DC 20460

Attention: Section 8(e) Coordinator (CAP Agreement)

RE: 8E CAP - 0024

Dear Section 8(e) Coordinator:

Enclosed are triplicate copies of a study CIBA-GEIGY Corporation is submitting pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement number 8E CAP-0024. The information being submitted is not considered Confidential Business Information. We are submitting the following information, as required by the CAP Agreement:

Company Name: CIBA-GEIGY Corporation

444 Saw Mill River Road

Ardsley, New York 10502-2699

Attention:

Mr. Anthony Di Battista

Manager, Regulatory Affairs & Toxic Substances

Compliance

Telephone (914) 479-2776

Tested Chemical: Coconut fatty acid amide of diethanolamine; also identified as Eriopon H

CAS No.: 68603-42-9

Report Title: Evaluation of Dermal Effects (I.B.L. No. 11360, dated 12/26/72)

Summary: A group of 200 individuals were exposed to a mixture of test materials under occlusion for two days a week for four weeks. Two weeks later, each contact site was challenged with the composite material for 48 hours after which the sites were graded. Composites which elicited reations during the test were separated into individual components for re-challenge on reacting individuals. Visible skin changes signifying reactions were observed in 5 of the 200 subjects. On re-challenge, one of





the components found responsible was the test material identified as Eriopon H. This study is submitted based on the demonstrated human sensitization potential that may have occurred. The reported chemical substance is no longer a commercial product.

The skin sensitiziting potential of the other test material associated with a positive response in this study, identified as Alrosperse 100, has been submitted under the TSCA 8(e) CAP in a separate letter.

Category: Unit II.B.2.a

Prior Reporting: Not Applicable

Please call the undersigned at telephone number (919) 632-2889 if you have any questions about this submittal.

Very Truly Yours,

Joseph A. LoMenzo, Ph.D.

Product Stewardship Director

Textile Products Division

Enclosures

2 copies of this letter

3 copies of the study

cc: A. Di Battista

## ID# 00260

# Food and Drug Besearch Laboratories



Maurice Avenue at 58<sup>th</sup> Street Maspeth, New York 11878 Telephone .212-894-0400 Cable Foodlate, New York

<: 3.CH00

Industrial Biology Durision 151 E. 10th Avenue, P.O. Box 424 Conshohocken, Pa. 19428 Telephone (215) 825-0517

Subject:

Evaluation of Dermal Effects

JAN 12 1973

December 26, 1972

Company:

CIBA-GEIGY Corporation Ardsley, New York 10502

Test

Materials: CIB

CIBA-GEIGY Name and Identification

I. B. L. No.

Phobotex FTC New Silvatol SO Alrosperse 100 -Eriopon H 11357 11358 11359

11360

Assay:

Repeated Insuit Patch Test

Study

Authorized:

13 April 1972

Material

Received: 1 May 1972

Purpose:

To determine if the test material is capable of irritating the skin of humans under controlled test conditions; and, if so, to classify the test material as a primary itritant, fatiguing agent, and or sensitizer on the basis of the visible clinical responses.

Panel Nos.:

251/72, 252/72, 258/72, 259/72

Procedure:

A group of 200 individuals who qualified were selected from a local population. All of these individuals volunteered to participate in this evaluation. The criteria for qualifying were:

- 1. General well being.
- 2. Absence of any skin diseases which might be confused with skin reactions from the test material.
- 3. Willingness to cooperate.
- 4. Dependability and intelligence in following directions.
- 5. Reading, understanding, and signing an informed-consent contract. (In the case of minors, parental consent was obtained.)

#### Food and Drug Besearch Laboratories in



INDUSTRIAL BIOLOGY DIVISION

Subject: Company: Evaluation of Dermal Effects CIBA-GEIGY Corporation

December 26, 1972

Procedure: (Cont'd)

The test materials were applied under occlusion for a series of effective contact periods of two days' duration, i.e., Monday to Wednesday and Wednesday to Friday of each week for four weeks. On Mondays, the test materials were applied. On Wednesdays, the patches were removed, the contact sites examined, and the test materials re-applied for another forty-eight-hour period. On Fridays, the covers were removed and the contact sites were again examined and graded. The contact sites were then rested until the following Monday.

A mixture of the group of four materials was applied to a single predesignated contact site which was reserved for this specific group throughout the test. On each application day, 4% aqueous solutions were freshly made. Fifty ml of the solutions of each of the four test materials comprising each group were then mixed together and one ml was pipetted off to saturate a lintine disc, 1.25 inch in diameter. One such disc was placed intimately in contact with the contact site on each participant and covered with a water impermeable sheet of plastic (1.5 inch by 1.5 inch). The plastic was then affixed to the skin with Blenderm tape applied in such a manner as to seal the edges and maintain the integrity of the micro-climate under the patch.

On the second Monday following the removal of the last series of applications, each contact site was challenged with its corresponding composite of test materials. The covers were removed on Wednesday, thereby effecting a challenge contact period of forty-eight hours' duration. The contact sites were examined for visible changes which, if present, were graded and recorded. Sites were re-examined twenty-four and forty-eight hours later for delayed reactions.

Composites which elicited reactions during the test were separated into individual components for re-challenge on reacting individuals. Results of these re-challenge applications are appended.

At all reading periods, it was found useful to wash the sites in order to remove the dyestuits obscuring the underlying skin. Mild, gentle sponging with warm water was found to be satisfactory.

#### Food and Drug Besearch Laboratories inc



INDUSTRIAL BIOLOGY DIVISION

Subject: Company: Evaluation of Dermal Effects CIBA-GEIGY Corporation

December 26, 1972

Results:

Visible skin changes signifying reaction to injury were observed in 5 of the 200 subjects during the series of application or following the challenge application. On re-challenge, the components found to be responsible were Alrosperse 100 and Eriopon II.

Conclusions:

Despite the reactions elicited by the composite and/or the components contained therein, because of the unusual conditions of the test, it is the opinion of the investigator that the results must be interpreted as indicative of having potential rather than mandatory irritating capabilities.

INDUSTRIAL BIOLOGY DIVISION

MORRIS V. SHELANSKI, M.D., C.M.

Director

#### Food and Drug Besearch Kabonatories.



INDUSTRIAL BIOLOGY DIVISION

Subject: Company: **Evaluation of Dermal Effects** CIBA-GEIGY Corporation

December 26, 1972

Material:

Composite: Phobotex FTC New, Silvatol SO,

I.B.L.Nos. 11357 - 11360

Alrosperse 100, Eriopon H

#### SUMMARY OF REACTION GRADES\*

Number of subjects negative Number of subjects showing reactions 195

		Num	her of Reaction	ons in Grades	Indicated	
Number of		1+	2+	3+	4+	NP
<b>Application</b>	0					
_	199	0	1	0	0	0
1		1	2	0	0	0
2	197	0	1	1	0	0
3	196	2	1	1	0	3
4	<b>19</b> 5	0	1	1	0	5
5	195	0	0	0	0	5
6	195	0	0	0	Ü	•
2	195	0	0	0	0	5
0	195	0	0	0	0	5
8	195	0	0	0	0	5
9		0	0	0	0	5
10	195	0	0	0	0	5
11	195	0	0	0	0	5
12	195	0	0	0	0	5
13	195	0	U	U	0	5
14	195	0	0	0	0	_
15	195	0	0	0	0	5
Challenge	195	0	0	0	0	5

#### \*Scoring Criteria:

0 = No reactions.

1+ = Slight erythema.

2+ = Marked erythema.

3+ = Marked erythema, edema, with or without a few vesicles.

4+ = Marked erythema, edema, with vesicles and oozing.

NP = No patch.

#### Food and Drug Research Kabenateries inc



#### INDUSTRIAL BIOLOGY DIVISION

Subject: Company: Material: **Evaluation of Dermal Effects CIBA-GEIGY Corporation** 

Composite: Phobotex FTC New, Silvatol SO,

Alrosperse 100, Eriopon H

December 26, 1972 I.B.L.Nos. 11357 - 11360

#### INDIVIDUAL REACTIONS

#### Exposure Number

Subject Number	1	2	3			6	7	ų	.9	10	11	12	13	14	15	С
3	0	0	0	(•	Ů	0	0	0	0	0	0	Ú	O	U	0	0
1 2	0	1+	2+	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP
3	0	0	ΰ	Ü	(;	0	0	U	0	0	0	G	0	0	0	6
4	0	0	ύ	(·	J	Ü	0	0	0	0	0	Ò	Ü	0	0	Û
5	Ò	0	0	0	Ó	0	0	0	0	0	0	0	0	Ú	0	G
6	0	0	0	0	Q.	Ú	0	0	0	0	0	0	0	0	0	(i
7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ห ห	0	0	0	e	0	0	0	Ú	0	0	0	0	0	0	0	Û
9	0	0	0	C	0	0	0	0	0	0	0	Ü	o	Ų	0	U
10	0	0	(1	6	0	0	0	0	0	0	0	0	0	0	G	Ú
11	0	0	c	c	(1	Ó	0	0	0	0	0	Ü	c	0	e	c
12	0	0	0	0	0	0	0	0	0	0	Ú	0	U	(i	0	(c
13	0	Ú	0	0	0	0	0	0	0	O	0	U	0	Ú	0	9
14	Ü	0	0	0	U	0	0	0	0	0	0	0	U	0	0	Ü
15	0	0	0	Ú	Ú	0	0	0	0	0	0	0	Ü	0	U	Ú
16	0	Ú	0	Ú	0	Ú	0	0	0	Ø	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	Ü	o	0	Û	U	$\epsilon_{\theta}$	0	0	U	0	0	0	0	Ü	O	Ú
19	0	Ú	C	0	Ù	Ú	0	0	0	O	0	0	0	0	U	G
20	0	0	0	0	0	0	0	0	0	0	0	0	0	Ú	0	Ú
21	0	0	0	0	Ú	Ú	0	0	0	0	0	0	U	0	0	0
22	0	ù	0	Ú	0	U	0	0	0	0	0	Ú	ŋ	0	O	0
23	0	0	Ó	Ü	Ü	;)	0	0	0	0	0	Ü	U	0	0	Ú
24	0	0	0	0	U	()	0	0	0	0	0	(1	0	£1	(,	()
25	0	0	Ü	0	o	0	. 0	Ü	0	0	0	O	O	O	U	(,
20	v	• • • • • • • • • • • • • • • • • • • •	_													

Underlined = Change of site.

NP = No patch.

## Food and Drug Besearch Laboratories, we



INDUSTRIAL BIOLOGY DIVISION

Subject:

**Evaluation of Dermal Effects** 

Company: CIBA-GEIGY Corporation

Material: Composite: Phobotex FTC New, Silvatol SO,

Alrosperse 100, Eriopon H

December 26, 1972 I.B. L. Nos. 11357 - 11360

#### INDIVIDUAL REACTIONS

#### Exposure Number

Cultinat				•												
Subject Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	C
Mullioer					•											
26	0,	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	2+	2+	D3 +	NP	NP	NP	NP	NP								
28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	G
30	0	0	0	Ú	0	0	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	O	0	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0	U	0	0	0
35	0	0	0	0	Ú	0	0	0	0	0	0	0	0	0	Ú	0
36	0	0	0	3+	NP	NP	NP	NР	NP	NP	NP	NP	NP	NP	NP	NP
37	ŏ	Ō	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	G	0
41	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
44	. 0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	Ú	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	()	0	0	0	0
48	0	0	0	0	0	0	0	(	0	0	0	$\theta$	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	()	0	6	0	0
50	0 ·	0	0	0	0	0	0	0	U	0	0	0	0	0	0	0

NP = No patch.

Underlined = Change of site.

D = Delayed reaction.

#### Food and Drug Besearch Kastonatries, Inc



INDUSTRIAL BIOLOGY DIVISION

Subject: Company: Evaluation of Dermal Effects CIBA-GEIGY Corporation

Material: Composite: Phobot

Composite: Phobotex FTC New, Silvatol SO,

Alrosperse 100, Eriopon H

December 26, 1972 I.B.L.Nos. 11357 - 11360

#### INDIVIDUAL REACTIONS

#### Exposure Number

Subject																
Number	. 1	2	3	4	_5_	6	7	8	9	10	11	12	13	14	15	C
51	0	0	0	0	0	0	0	0	0	0	0	0	0	0	()	()
52	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ü	0
53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0 .	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
57	0	2+	1-	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP	NF
58	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0	0	O	0	0
61	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	O
64	0	Ó	0	0	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0	0	Ú	0	0
69	0	0	J	0	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	O)	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Underlined = Change of site. NP = No patch.

#### Food and Drug Bessearch Laboratories, mc

#### INDUSTRIAL BIOLOGY DIVISION

Subject: Company: Evaluation of Dermal Effects CIBA-GEIGY Corporation

Material:

Composite: Phobotex FTC New, Silvatol SO,

Alrosperse 100, Eriopon H

December 26, 1972

I.B.L.Nos. 11357 - 11360

#### INDIVIDUAL REACTIONS

Subject																
Number	1	2	3	-1	5	6	7	ß	9	10	11	12	13	14	15	С
76	0	0	0	0	0	0	0	0	0	0	0	0	c	0	0	e
77	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
78	0	0	0	0	6	0	0	0	0	0	0	0	0	0	0	Ú
79	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0	0	0	0	0	Ú	0	Ú	0
81	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ç
82	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Ú
83	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
84	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
86	0	0	()	U	0	0	0	0	0	0	0	0	0	0	0	0
87	0	0	0	0	0	0	O	0	0	0	0	0	0	0	0	0
88	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
91	0.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
93	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
94	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
95	0	0	0	0	0	0	0	0	0	0	0	0	^	0	0	0
96	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
97	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
98	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
99	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

#### Food and Drug Besearch Laboratories, in



#### INDUSTRIAL BIOLOGY DIVISION

Subject: Company: Evaluation of Dermal Effects CIBA-GEIGY Corporation

Material:

Composite: Phobotex FTC New, Silvatol SO,

Alrosperse 100, Eriopon H

December 26, 1972

I.B. L. Nos. 11357 - 11360

#### INDIVIDUAL REACTIONS

#### Exposure Number

	the state of the s															
Subject																
Number	1	2	3_	_4_	5	6			9	10	11	12	13	14	15	<u>C</u>
101	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
102	0	0	0	0	Ú	0	0	0	0	0	0	0	0	0	0	0
103	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
104	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
105	0	0	0	0	0	0	0	(1	0	0	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
108	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
109	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	1+	2+	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP	NP
111	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
112	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
113	0	0	0	0	0	0	0	0	O	0	0	0	0	0	0	0
114	. 0	0	0	0	0	0	0	0	()	a	0	0	0	0	0	0
115	0	0	0	o	0	0	0	0	0	Ŏ.	0	0	0	0	0	0
116	0	0	0	0	O	0	0	0	0	0	Ó	0	0	0	0	0
117	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
118	0	0	0	0	0	0	0	0	0	0	0	0	0 -	0	. 0	0
119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
120	0	0	0	0	0	0	0	0	0	0	0	Ü	0	0	0	0
121	0	0	0	0	0	0	$\theta$	0	0	0	0	0	0	0	0	0
122	0	0	0	0	0	0	Ò	0	0	0	0	0	0	0	0	0
123	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No patch = NP.

## Food and Drug Besearch Kabonatories, INC



#### INDUSTRIAL BIOLOGY DIVISION

Subject:

Evaluation of Dermal Effects CIBA-GEIGY Corporation

Company: Material:

Composite: Phobotex FTC New, Silvatol SO,

Alrosperse 100, Eriopon H

December 26, 1972 I.B. L. Nos. 11357 - 11360

## INDIVIDUAL REACTIONS

Exposure																
ıbject umber	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	С
unioci								^	0	0	0	0	0	Ó	0	0
<b>12</b> 6	0	0	0	0	9	0	0 .	0		0	0	0	0	Ú	0	0
127	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
128	0	0	0	G	0	0	0	0	0	0	0	0	0	0	Ű	0
129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
130	0	0	0	0	0	0	0	0	0		0	Û	0	0	0	0
131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	ő	0
132	0	0	0	0	0	0	0	0	0	0	_		0	0	0	0
133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
134	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0
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145	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	(
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150	0	0	0	0	0	0	0	0	0	0	0	1)	0	0	0	,

## Food and Drug Bessearch Laboratories, INC

INDUSTRIAL BIOLOGY DIVISION

Subject: Company: Evaluation of Dermal Effects CIBA-GEIGY Corporation

Material:

Composite: Phobotex FTC New, Silvatol SO,

Alrosperse 100, Eriopon H

December 26, 1972 I.B. L. Nos. 11357 - 11360

#### INDIVIDUAL REACTIONS

Subject										10	11	12	13	14	15	$\overline{c}$
Number	1		3	4	5	<u> 6</u>		<u> 5</u>	9	10	11	14	1.0	14	10	
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153	0	0	0	0	0	0	G	0	0	0	0	0	0	0	0	0
154	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9
155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
156	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
157	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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165	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
170	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
171	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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#### Food and Drug Besearch Laboratories inc



#### INDUSTRIAL BIOLOGY DIVISION

Subject:

Evaluation of Dermal Effects CIBA-GEIGY Corporation

Company: Material:

Composite: Phobotex FTC New, Silvatol SO,

Alrosperse 100, Eriopon H

December 26, 1972

I.B. L. Nos. 11357 - 11360

#### INDIVIDUAL REACTIONS

Subject																
Number	1	2	_3_	4	_ <u>5</u>	_6_			9	10	11	12	13	14	15	<u>C</u>
176	0	0	G	Ò	Ģ	0	0	0	Û	0	U	<b>f</b> 1	0	0	6	C
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181	0	0	0	O	Ġ	6	0	0	0	0	0	0	6	0	0	0
182	0	0	0	0	0	0	0	0	0	0	0	0	e	0	0	0
183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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185	0	0	0	0	(i	O	0	0	0	0	0	0	0	0	0	0
186	0	0	0	0	$\mathbf{f}^{\cdot}$	0	0	0	0	0	0	0	0	0	0	0
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INDUSTRIAL BIOLOGY DIVISION

Signetti Company: Evaluation of Dermal Effects CIBA-GEIGY Corporation

December 26, 1972

## REACTIONS TO INDIVIDUAL COMPONENTS OF THE COMPOSITE MATERIAL

Subject Number	Phobotex FTC New I. B. L. No. 11357	Silvatol SO 1. B. L. No. 11358	Alrosperse 100 I.B.L.No. 11359	Eriopen H I. B. L. No. 11360
2	0	0	0	3+
27	0	0	o	2-
36	0	o	0	0
57	0	0	1 +	0
110	0	0	1+	0



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#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Joseph A. LoMenzo, Ph.D. Product Stewardship Director **Textile Products Division CIBA-GEIGY Corporation** P.O. Box 18300 Greensboro, North Carolina 27419-8300

OFFICE OF PREVENTION, PESTICIDES AND **TOXIC SUBSTANCES** 

APR 1 8 1995

EPA acknowledges the receipt of information submitted by your organization under Section 3 (e) of the Toxic Substances Co trol Act (TSCA). For you reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests" .

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confiden-This same enclosure is used to support tiality Claims". confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

> Document Processing Center (7407) Attn: TSCA Section 8(e) Coordinator Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

eny R. C. Byon Terry R. O'Bryan

Risk Analysis Branch

Enclosure

12301A

## Triage of 8(e) Submissions

Date sent to triage:	APR 2 0 1995	N	ON-CAP	CAP	
Submission number: _	123014	TS	GCA Inventory:	Y N	D
Study type (girale one	ronrintol				
Study type (circle app					
Group 1 - Dick Cleme	, ,,				
ECO	AQUATO				
Group 2 - Ernie Falke	(1 copy total)				
ATOX	SBTOX SEN	w/NEUR			
Group 3 - Elizabeth M	largosches (1 copy each)				
STOX	CTOX EPI	RTOX	GTOX		
STOX/ONCO	CTOX/ONCO IMMUNO	СҮТО	NEUR		
Other (FATE, EXPO, M	ET, etc.):				
Notes:					
THIS IS THE ORIGIN	IAL 8(e) SUBMISSION; PLEAS	E REFILE A	FTER TRIAGE	DATABASE EN	TRY
					MARIAN I
	For Contractor	Use Only			
entire document:	0 <i>6</i> 2 pages <u>42</u>		pages/_	2/14 7/1	}
Notes:					
Contractor review	ver : RW	Date:	4/3/9		

## CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8EHQ- 1192-12301  TYPE: (NT) SUPP FLWP  SUBMITTER NAME: C1ba-Geign  Corporatio	seq. A	INFORMATION REQUESTED: FLWI 0501 NO INFO REQUESTED 0502 INFO REQUESTED (TECH) 0503 INFO REQUESTED (VOL ACT 0504 INFO REQUESTED (REPORTION: DISPOSITION: 0639 REFER TO CHEMICAL SCREE 0678 CAP NOTICE	IONS) NG RATIONALE)	VOLUNTARY ACTIONS:  0407 NO ACTION RU PORTILI 0402 STUDIES PLANNEDAIN 0403 NOTIFICATION OF WO 0404 LABELANSDS CHANGE 0405 PROCESSAIANDLING O 0406 APPAUSE DISCONTINU 0407 PRODUCTION DISCON 0408 CONFIDENTIAL	IDI RWAY RKI R OTHI HS S HANGI S IED
SUB. DATE: 1009 90 01	S DATE: 11 02/92	CSRAD DATE: 03	06/95		
Enlopon H			8603-42-C		
INFORMATION TYPE:	P.F.C INFOR	MATION TYPE:	PFC INF	ORMATION TYPE:	<u>P F C</u>
0201 ONCO (HUMAN) 0202 ONCO (ANIMAL) 0203 CELL TRANS (IN VITRO) 0204 MUTA (IN VITRO) 0205 MUTA (IN VIVO) 0206 REPRO/IERATO (HUMAN) 0207 REPRO/TERATO (ANIMAL) 0208 NEURO (HUMAN) 0209 NEURO (ANIMAL) 0210 ACUTE TOX. (HUMAN) 0211 CHR. TOX. (HUMAN) 0212 ACUTE TOX. (ANIMAL) 0213 SUB ACUTE TOX (ANIMAL) 0214 SUB CHRONIC TOX (ANIMAL) 0215 CHRONIC TOX (ANIMAL)	01 02 04 0216 01 02 04 0217 01 02 04 0218 01 02 04 0229 01 02 04 0221 01 02 04 0221 01 02 04 0222 01 02 04 0223 01 02 04 0223 01 02 04 0225 01 02 04 0225 01 02 04 0227 01 02 04 0228 01 02 04 0229 01 02 04 0228	EPI/CLIN HUMAN EXPOS (PROD CONTAM) HUMAN EXPOS (ACCIDENTAL) HUMAN EXPOS (MONITORING) ECO/AQUA TOX ENV. OCCCREL/FATE EMER INCI OF ENV CONTAM RESPONSE REQEST DELAY PROD/COMP/CHEM ID REPORTING RATIONALE CONFIDENTIAL ALLERG (HUMAN) ALLERG (ANIMAL) METAB/FHARMACO (ANIMAL)	01 02 04 0241 01 02 04 0242 01 02 04 0244 01 02 04 0244 01 02 04 0244 01 02 04 0244 01 02 04 0244 01 02 04 0244 01 02 04 025 01 02 04 025 01 02 04 025 01 02 04 025 01 02 04 025	IMMUNO (HUMAN) CHEM/PHYS PROP CLASTO (IN VITRO) CLASTO (ANIMAL) CLASTO (HUMAN) DNA DAM/REPAIR PROD/USE/PROC MSDS	01 02 04 01 02 04
TRIAGE DATA: NON-CBI INVENTORY YES	ONGOING REVIEW YES (DROP/REFER)	Serv SPECIES TOXICOLOGICA HATAL DOSE	AL CONCERN:	<u>use:                                    </u>	TION:
CAS SR NO	NO (CONTINUE)	MED			

(UMMERI)

8(E)-12301A

Η

DERMAL SENSITIZATION IN HUMANS IS OF HIGH CONCERN BASED ON SLIGHT TO MARKED ERYTHEMA (5/200) AT CHALLENGE (1 ML) FOLLOWING OCCLUDED EXPOSURE TO 1.0 ML TWICE/WEEK FOR 4 WEEKS AND A REST PERIOD OF 2 WEEKS.



Tox Concern				
ID	GEN	1	L(EPI)	
12301A	SEN EPI		H(SEN)	
COMMENT	NO 10 OF HIGH	CONCERN BASE	ON SUCHT TO MAD	OKED.
SEN: DERMAL SENSITIZATION IN HUMANS IS OF HIGH CONCERN BASED ON SLIGHT TO MARKED ERYTHEMA (5/200) AT CHALLENGE (1 ML) FOLLOWING OCCLUDED EXPOSURE TO 1.0 ML TWICE/WEEK FOR 4 WEEKS AND A REST PERIOD OF 2 WEEKS.				
EPI: THE CHEMICAL WAS TESTED FOR POTENTIAL SKIN SENSITIZATION AND 5 OF 200 SUBJECTS REACTED POSITIVELY. THE CHEMICAL HAS BEEN WITHDRAWN FROM COMMERCE.				
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